

MAR 17 2000

## 510(k) SUMMARY

K000077

### Submitter Information.

Raymond Ursick  
Vice President, Regulatory Affairs and Quality Systems  
5960 Heisley Road  
Mentor, Ohio 44060  
(440) 354-2600  
Date Summary Prepared: February 20, 2000

### Introduction

The Amsco brand Millennium Steam Sterilizer is a Class II medical device as defined by 21 CFR §880.6880. The Millennium Steam Sterilizer is intended for the terminal sterilization of non-porous and porous, heat and moisture-stable materials in healthcare facilities.

The Millennium Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values:

CYCLES	RECOMMENDED LOAD	STERILIZE TEMP.	STERILIZE TIME	DRY TIME
FLASH	Unwrapped Instrument tray with a single instrument. Non-porous goods only.	270°F (132°C)	3 minutes	1 minute
WRAPPID/ EXPRESS	Single-wrapped instrument tray with a single instrument. Non-porous goods only.	270°F (132°C)	4 minutes	3 minutes
WRAPPID/ SFPP	Up to two double-wrapped instrument trays, maximum weight 17 lbs each. Non-porous goods only.	270°F (132°C)	4 minutes	20 minutes
SFPP	Up to six (6) fabric packs.	270°F (132°C)	4 minutes	20 minutes*

\*For processing a single fabric pack, a 5-minute Dry Time can be used.

In addition to the above-reference factory set sterilization cycles, the Millennium Sterilizer also offers four customer-selectable cycles:

CYCLES	RECOMMENDED LOAD	STERILIZE TEMP.	STERILIZE TIME	DRY TIME
PREVACUUM	Up to two double wrapped-instrument trays, maximum weight 17 lbs. each. Up to six (6) fabric packs.	270°F (132°C)	4 minutes	20 minutes
GRAVITY	Up to two double wrapped instrument trays, maximum weight 17 lbs. each.	270°F (132°C)	15 minutes	30 minutes
GRAVITY	Up to six (6) fabric packs.	250°F (121°C)	30 minutes*	15 minutes
FLASH	Unwrapped instrument tray with multiple instruments, maximum weight 17 lbs. Non-porous goods only.	270°F (132°C)	10 minutes	1 minute

\*For processing fabric packs, a 270°F cycle adjusted to 25-minute Sterilize time can be used.

### **Effectiveness**

Efficacy of sterilizer function and exposure time recommendations are ultimately shown by complete kill of biological indicators and verifying an appropriate safety factor or sterility assurance level (SAL) of less than  $10^{-6}$  (probability of less than one chance out of one million of a non-sterile indicator). STERIS validates its sterilization cycles by recommended practices, standards and guidelines developed by various independent organizations such as the Association for Advancement of Medical Instrumentation (AAMI).

The results of the Millennium Validation demonstrate that the sterilizer performs as intended and are summarized as follows:

- All SFPP cycles validated using the fabric test pack, as described in Section 5.5.1.1 of AAMI/ANSI-ST8, were qualified according to Section 5.5.1 AAMI/ANSI-ST8. These cycles demonstrated a sterility assurance level of at least  $10^{-6}$  through achievement of a time-at-temperature sufficient to produce an  $F_0$  value of at least 12, and a moisture retention of less than 3% increase in presterilization test pack weight, and exhibited no wet spots.
- All SFPP cycles validated using full load instrument trays were qualified according to Section 5.5.3 of AAMI/ANSI-ST8. These cycles demonstrated a sterility assurance level of at least  $10^{-6}$  by  $\frac{1}{2}$  cycle analysis, a moisture retention of less than 20% increase in the presterilization weight of the towel, and exhibited no wet spots on the outer wrapper.
- All SFPP cycles validated using a single wrapped tray with a single instrument were qualified using appropriate test methods to meet the definition of Section 2.19 of AAMI/ANSI-ST 37 with a demonstrated sterility assurance level of at least  $10^{-6}$  by  $\frac{1}{2}$  cycle analysis.
- All customer-selectable prevacuum cycles validated using the Bowie-Dick Test Pack were qualified according to Section 5.6 of AAMI/ANSI-ST8, and demonstrated a uniform color change throughout the test sheet.
- The software validation for the revised program was performed according to FDA's moderate level of concern recommendations provided in the document "*Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices (5/29/98)*".

### **Safety**

STERIS brand sterilizers including the Millennium Steam Sterilizers have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The Millennium Steam Sterilizer complies with the following requirements:

- Underwriters Laboratory (UL) Electromedical Code 544 as certified by ETL Testing Laboratories, Inc.
- Canadian Standards Association (CSA) Standard C22.2 No. 125 or 151.
- American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels.
- American Society of Mechanical Engineers (ASME), Section I, Part PMB for power boilers.
- California Seismic Pre-Approval.
- National Fire Protection Association Standard 99.

A Fault Tree Analysis and Failure Modes and Effects and Criticality Analysis has been conducted on the Eagle Century Steam Sterilizer's electrical system, mechanical system and piping system which is identical to the Millennium Sterilizer electrical, mechanical and piping systems.

### **Hazards-Failure of Performance**

Failure of the sterilization process can lead to incidence of cross contamination, the transmission of potentially infectious organisms from one infected person to another who was not otherwise infected

prior to the incident.

To avoid failure, the user must ensure the materials, instruments and devices to be sterilized are thoroughly cleaned, that the manufacturer's instructions for use are followed, that the cycle to be used for each type of sterilizer load has been validated, that the sterilizer has been maintained in accordance with the sterilizer manufacturer's recommended maintenance schedule and is operating properly, and that each sterilizer load is monitored with available and validated biological and chemical sterilization process indicators.

Today, there are many steam sterilizers in daily use in hospitals throughout the United States. The incidence of sterilizer malfunction or sterilization process failure is relatively rare considering the widespread use of steam sterilizers. Further, there are no known reports in the literature of patient infections that have resulted from steam sterilizer failure. The technology designed in STERIS brand steam sterilizers including the Millennium provides microprocessor controller safeguards that abort the cycle and give appropriate signals, alerts and warnings when required conditions have not been met or when a malfunction occurs.

#### **User Information**

STERIS conducts in-house user training and has developed a series of user training videos that provide helpful information about the appropriate use of steam sterilizers. STERIS further provides information to the user that is intended to ensure safe and effective use of steam sterilization in its detailed Operator's Manual and other labeling. STERIS also recommends the use and periodic review of the AAMI steam sterilization standards to ensure further assurance of the safe and effective use of steam sterilization equipment in health care facilities.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 17 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Raymond Ursick  
Vice President Regulatory Affairs  
and Quality Systems  
Steris Corporation  
5960 Heisley Road  
Mentor, Ohio 44060-1834

Re: K000077

Trade Name: Steris® Amsco® Millennium Steam Sterilizer  
Regulatory Class: II  
Product Code: FLE  
Dated: February 29, 2000  
Received: March 2, 2000

Dear Mr. Ursick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

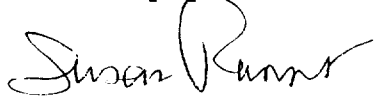
Page 2 -Mr. Ursick

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
Ed Timothy A. Ulatowski

Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K000077

**INDICATIONS FOR USE STATEMENT**  
**DEVICE NAME: MILLENNIUM STEAM STERILIZER**

**INDICATIONS FOR USE:**

The Millennium Sterilizer is intended to sterilize non-porous and porous, heat and moisture-stabile materials used in healthcare facilities. The Millennium Sterilizer is available in the following configurations:

16"x16"x26"	Single Door	16"x16"x26"	Double Door
20"x20"x38"	Single Door	20"x20"x38"	Double Door

The Millennium Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values:

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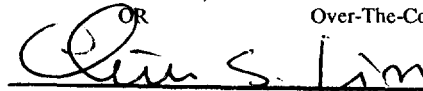
CYCLES	RECOMMENDED LOAD	STERILIZE TEMP.	STERILIZE TIME	DRY TIME
PREVACUUM	Up to two double wrapped-instrument trays, maximum weight 17 lbs. each. Up to six (6) fabric packs.	270°F (132°C)	4 minutes	20 minutes
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Prescription Use \_\_\_\_\_  
 (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)  
 OR  
 Over-The-Counter Use \_\_\_\_\_



(Division Sign-Off)

Division of Dental, Infection Control,  
 and General Hospital Devices

510(k) Number

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(Optional Format 1-2-96)